K100067



## 510(k) Summary

JAN 28 2010

**Submitter's Name:** Toshiba America Medical Systems, Inc.
**Address:** 2441 Michelle Drive, Tustin, CA 92780
**Contact:** Paul Biggins, Director Regulatory Affairs
**Telephone No.:** (714) 730-5000

**Device Proprietary Name:** VIAMO MODEL SSA-640A Version 2.0
**Common Name:** Diagnostic Ultrasound System

**Classification:**

- **Regulatory Class:** II
- **Review Category:** Tier II

- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [Fed. Reg.No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [Fed. Reg.No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [Fed. Reg. No.: 892.1570]

**Identification of Predicate Devices:**
Toshiba America Medical Systems believes that this device is substantially equivalent to:

- Toshiba Ultrasound Diagnostic System Viamo Model SSA-640 v1.2 – 510(k) K093171
- Toshiba Ultrasound Diagnostic System Aplio XG Model SSA-790A V4.0 - 510(k) K091295

**Device Description:**
The Viamo is a mobile system. It is a Track 3 device that employs a wide range of probes that include flat linear array, convex array and sector array with a frequency range of approximately 2.5 MHz to 12 MHz.

**Intended Use:**
The Viamo SSA-640 v2.0 Ultrasound System is indicated for the visualization of structures, characteristics, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, trans-vaginal neonatal cephalic, adult cephalic, cardiac, peripheral vascular, and musculo-skeletal (both conventional and superficial).

**Declaration of Conformity:**
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 28 2010

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K100067
Trade/Device Name: Viamo SSA-640 v2.0 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: January 8, 2010
Received: January 11, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Viamo SSA-640 v2.0 Ultrasound System, as described in your premarket notification:

Transducer Model Number

| | | |
|---|---|---|
| PLT-704AT | PVT-674BT | PLT-704ST |
| PVT-705BTH | PLT-1204BT | PVT-375ST |
| PVT-745BTV | PVT-382BT | PST-25ST |
| PVT-661VT | PLT-805AT | |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

# Indications for Use

510(k) Number (if known): K100067

Device Name: Viamo SSA-640 v2.0 Ultrasound System

Indications for Use:

The Viamo SSA-640 v2.0 Ultrasound System is indicated for the visualization of structures, characteristics, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, pediatric, small organs, trans-vaginal, neonatal cephalic, adult cephalic, cardiac, peripheral vascular, and musculo-skeletal (both conventional and superficial).

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A

Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Advanced Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Small Organ (Note 1) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Neonatal Cephalic | P | P | P | | P | 2 | P | N | P | | | 3 |
| Adult Cephalic | P | P | P | | P | 2 | P | N | P | | | 3 |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | N | N | N | | N | 2 | N | N | N | | | 3 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | | P | 2 | P | N | P | | | 3 |
| Cardiac Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | N | P | | | 3 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k): K093171

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure: added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PST-25ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specific (Tracks 3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Combined (Specify) *** | **THI** | **Advanced Dynamic Flow** | **Power** | **CHI 2D** | **4D** | **Other [Note]** |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Small Organ (Note 1) | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | | P | 2 | P | N | P | | | 3 |
| Adult Cephalic | P | P | P | | P | 2 | P | N | P | | | 3 |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | | P | 2 | P | N | P | | | 3 |
| Cardiac Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K093171

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PVT-375ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specific (Tracks 3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Combined (Specify) *** | **THI** | **Advanced Dynamic Flow** | **Power** | **CHI 2D** | **3D** | **Other [Note]** |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal **(Conventional)** | | | | | | | | | | | | |
| Musculo-skeletal **(Superficial)** | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K093171

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100017

System: Viamo v4.0 SSA-640A
Transducer: PLT-704ST

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specific (Tracks 3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Combined (Specify) *** | **THI** | **Advanced Dynamic Flow** | **Power** | **CHI 2D** | **3D** | **Other [Note]** |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (**Conventional**) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Musculo-skeletal (**Superficial**) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | N | P | | | 3 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K093171

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100017

System: Viamo v2.0 SSA-640A
Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Advanced Dynamic Flow | Power | CHI 2D | 3D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | N | P | | | 3 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K093171

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specific (Tracks 3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Combined (Specify) *** | **THI** | **Advanced Dynamic Flow** | **Power** | **CHI 2D** | **3D** | **Other [Note]** |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal **(Conventional)** | | | | | | | | | | | | |
| Musculo-skeletal **(Superficial)** | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091371

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Advanced Dynamic Flow | Power | CHI 2D | 3D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | N | P | | | 3 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Advanced Dynamic Flow | Power | CHI 2D | 3D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | N | P | | | 3 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K180867

System: Viamo v2.0 SSA-640A
Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specific (Tracks 3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Combined (Specify) *** | **THI** | **Advanced Dynamic Flow** | **Power** | **CHI 2D** | **3D** | **Other [Note]** |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | N | N | N | | N | 2 | N | N | N | | | 3 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal **(Conventional)** | | | | | | | | | | | | |
| Musculo-skeletal **(Superficial)** | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100867

System: Viamo v2.0 SSA-640A
Transducer: PVT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Specific (Tracks 3)** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Combined (Specify) *** | **THI** | **Advanced Dynamic Flow** | **Power** | **CHI 2D** | **3D** | **Other [Note]** |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal **(Conventional)** | | | | | | | | | | | | |
| Musculo-skeletal **(Superficial)** | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | N | P | | | 3 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Advanced Dynamic Flow | Power | CHI 2D | 3D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | P | N | P | | | 3 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (**Conventional**) | | | | | | | | | | | | |
| Musculo-skeletal (**Superficial**) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

510(k) Number K100067

System: Viamo v2.0 SSA-640A
Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Specific (Tracks 3) | B | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Advanced Dynamic Flow | Power | CHI 2D | 3D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | P | N | P | | | 3 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | N | P | | | 3 |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K091295

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 ApliPure : added under this submission

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510(k) Number K100067